ASX ANNOUNCEMENT
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Australian Ethics Committee approval to expand PD-L1 nanobody (RAD204) Phase 1 Trial in multiple tumor types

- **The Human Research Ethics Committee (HREC) in Australia has approved the inclusion of five additional PD-L1 expressing solid tumors, beyond Non Small Cell Lung Cancer (NSCLC), for a Phase 1 therapeutic trial of RAD204.**
- **The ongoing Phase 1[1] First-In-Human study is designed to assess safety and tolerability of ^{177}Lu-RAD204 in individuals with PD-L1-positive advanced solid tumors.**
- **16 patients previously dosed in a Phase 1 diagnostic study demonstrated safety and biodistribution, validating the potential of ^{177}Lu-RAD204 for the treatment of advanced PD-L1 expressing cancers.**

Sydney, Australia – 19 November 2024 – Radiopharm Theranostics (ASX:RAD, "Radiopharm" or the "Company"), a clinical-stage biopharmaceutical company focused on developing innovative oncology radiopharmaceuticals for areas of high unmet medical need, is pleased to announce it has been granted Human Research Ethics Committee (HREC) approval to include participants with Programmed Death-Ligand 1 (PD-L1) positive Small Cell Lung Cancer (SCLC), Triple Negative Breast Cancer (TNBC), Melanoma, Head and Neck Cancer (HNSCC), and Endometrial Cancer, as part of its ongoing Phase 1 clinical trial of ^{177}Lu-labelled RAD204 for the treatment of PD-L1 expressing cancers.

The open-label Phase 1 trial, entitled "Phase 0/1 Study of the Safety and Tolerability of ^{177}Lu-RAD204, a Lutetium-177 Radiolabelled Single Domain Antibody Against Programmed Cell Death-Ligand 1 in Patients with Metastatic Solid Tumours", is a First-In-Human dose escalation trial of ^{177}Lu-RAD204[1], and is designed to evaluate the safety and preliminary clinical activity of this novel radiotherapeutic in eligible individuals with PD-L1 expressing advanced cancers.

The trial is currently ongoing and recruiting at four sites across New South Wales, South Australia and Western Australia, with the support of leading oncology care provider GenesisCare CRO.

RAD204 is a single-domain monoclonal antibody (sdAb) that targets PD-L1, a protein that helps control the immune system and is overexpressed in many solid cancers, making it an attractive therapeutic target in tumor types that include NSCLC, SCLC, TNBC, Cutaneous Melanoma, HNSCC, and Endometrial Cancer[2]. Previously published[3] Phase I imaging data of 16 NSCLC patients with RAD204 have demonstrated that the diagnostic compound is safe and is associated with acceptable dosimetry. Tumor targeting with radioimmunotherapies such as ^{177}Lu-RAD204 has the potential to address resistance mechanisms to current standard-of-care treatment options[4].

[1] **NCT06305962**: clinicaltrials.gov/study/NCT06305962?term=NCT06305962&rank=1
[2] Zaheer J, Kim H, Lee YJ, Kim JS, Lim SM. Combination Radioimmunotherapy Strategies for Solid Tumors. Int J Mol Sci. 2019 Nov 8;20(22):5579.
[3] Xing Y, Chand G, Liu C, Cook GJR, O'Doherty J, Zhao L, Wong NCL, Meszaros LK, Ting HH, Zhao J. Early Phase I Study of a ^{99m}Tc-Labeled Anti-Programmed Death Ligand-1 (PD-L1) Single-Domain Antibody in SPECT/CT Assessment of PD-L1 Expression in Non-Small Cell Lung Cancer. J Nucl Med. 2019 Sep;60(9):1213-1220.

"The implications of including additional PD-L1 expressing tumor types beyond NSCLC in this study is far-reaching," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "Patients with five additional PD-L1 expressing tumor types are now eligible for this basket trial, supporting the potential of ^{177}Lu-RAD204 for a tumor-agnostic indication and as an effective radioimmunotherapy based on a pan-tumor predictive biomarker. With RAD204, we hope to provide an alternative strategy that can improve clinical outcomes for patients with PD-L1 positive advanced cancers, while potentially preserving their quality of life."

About Radiopharm Theranostics

Radiopharm Theranostics is a clinical stage radiotherapeutics company developing a world-class platform of innovative radiopharmaceutical products for diagnostic and therapeutic applications in areas of high unmet medical need. Radiopharm has been listed on ASX (RAD) since November 2021. The company has a pipeline of six distinct and highly differentiated platform technologies spanning peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development from some of the world's leading universities and institutes. The pipeline has been built based on the potential to be first-to-market or best-in-class. The clinical program includes one Phase II and three Phase I trials in a variety of solid tumour cancers including breast, kidney and brain. Learn more at radiopharmtheranostics.com.

Authorized on behalf of the Radiopharm Theranostics Board of Directors by Executive Chairman Paul Hopper.

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